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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,424	05/30/2001	Anton-Lewis Usala	35626/234826	7082

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SUK

Office Action Summary	Application No.	Applicant(s)	
	09/870,424	USALA, ANTON-LEWIS	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *11,12,14,15,22-24,34,40,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13,16-21,25-33,35-39 and 41-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4/12/02 &* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

IDS Cont. 12/31/01.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the following species: denatured collagen, dextran, glutamic acid (or L-glutamic acid), cysteine (or L-cysteine), and EDTA, in the paper filed 10/31/03 is acknowledged. Claims 1-10, 13, 16-21, 25-33, 35-39, and 41-43 are drawn to the elected species and are examined on the merits. Claims 11,12,14,15,22-24,34,40,44 and 45 are withdrawn from consideration as being drawn to non-elected species.

Information Disclosure Statement

The information disclosure statement filed 12/31/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; *each publication* or that portion which caused it to be listed; and all other information or that portion which caused it to be listed (not found to be scanned into electronic file wrapper). It has been placed in the application file, but the information referred to therein has not been considered. Additionally, untranslated reference DE 44 31 598, was also not considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 26, it is not clear what is meant by EDTA. Although EDTA is known in the art as "ethylene diamine tetra acetate", a superoxide inhibitor, it is not known if the shortened acronym EDTA has been used to define any other compounds. In order to distinctly claim the invention, it is suggested that the first use of EDTA be put in parenthesis, behind the full spelling of the compound, "ethylene diamine tetra acetate".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 4, 7, 10, 25-26, and 28-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Naughton et al. (US 6372494 B1).

Naughton et al. teach a method of stimulating hair growth (col., 1, lines 14-15) using a hydrogel matrix (claim 9) composition comprising gelatin (collagen) and a long chain carbohydrate (dextran)(col. 11, lines 66-67); as well as amino acids such as glutamic acid (col. 9,

lines 4-12); and EDTA (col. 7, line 8); that may be injected (col. 26, line 13). [Note: Although Naughton et al. teach any amino acid generally, cysteine was not expressly claimed].

Claims 1-2, 4, 7, 10, 16-17, 25-26, 28, 30, 33, 35-36, 41-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Gentz et al. (US 6238888 B1).

Gentz et al. teach the use of formulations to stimulate hair follicle production (col. 21, lines 27-28) comprising collagen (col. 9, lines 34-45) and dextran (col. 9, line 29), glutamic acid (col. 13, line 5), cysteine (col. 4, lines 55), and EDTA (col. 13, line 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 13, 16-21, 25-33, 35-39, and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton et al. (US 6372494 B1) in view of Obi-Tabot (US 6046160).

Naughton et al. is discussed above. Although Naughton et al. teach the use of collagen, the reference does not expressly teach collagen as denatured (Applicant's claim 29). Also, although Naughton et al. teach the use of "any amino acid" (col. 9, lines 4-12), Naughton et al. does not expressly teach use of cysteine. Additionally, although Naughton et al. generally describe the use of the present invention's compounds in varying amounts, the reference does not

expressly teach all the various mM of collagen, Daltons of dextran, or mM of glutamic acid, or μM of cysteine (Applicant's claims 5-6, 8-9, 13, 18-21, 27, and 37-39).

Obi-Tabot generally teaches that collagen in skin treatments can be preferably denatured which can be "solubilized for easy application as a gelatin-like solution. When cooled, the collagen is partially renatured, resulting in a gel formation with excellent tensile strength", that can be easily injected (col. 13, lines 17-30).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use denatured collagen as the collagen of choice in the hydrogel for hair growth of Naughton et al. because Obi-Tabot teach the advantageous use of denatured collagen in skin treatment, since the denatured state may be easily applied/injected as a gelatin.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use cysteine in the hydrogel for hair growth of Naughton et al. because the use of cysteine as "any amino acid" is within the routine optimization by one of skill in the art and because Naughton et al. teach that any amino acid may be added to the hydrogel (col. 9, lines 4-12).

Additionally, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use various mM of collagen, Daltons of dextran, or mM of glutamic acid, or μM of cysteine in the hydrogel for hair growth of Naughton et al. because the additional of different amounts of such compounds for desired effects is well within the purview of one of skill in the art and a matter of routine optimization.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-10, 13, 16-21, 25-28, 30-33, and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gentz et al. (US 6238888 B1) in view of Obi-Tabot (US6046160).

Gentz et al. is discussed above. Although Gentz et al. teach the use of collagen, the reference does not expressly teach the use of denatured collagen (Applicant's claims 3 and 30).

Obi-Tabot is discussed above. Obi Tabot teach the use of denatured collagen.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use

Claims 1-10, 13, 16-21, 25-33, 35-39, and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gentz et al. (US 6238888) in view of Obi-Tabot (US6046160) and further in view of Naughton et al. (US 6372494).

Gentz et al. and Obi-Tabot are both discussed above. Gentz et al. does not expressly teach the injection of the composition (Applicant's claims 29 and 43). Additionally, although Gentz et al. generally describe the use of the present invention's compounds in varying amounts,

the reference does not expressly teach all the various mM of collagen, Daltons of dextran, or mM of glutamic acid, or μM of cysteine (Applicant's claims 5-6, 8-9, 13, 18-21, 27, and 37-39).

Naughton et al. is discussed above. Naughton et al. teach the injection of a hair growth composition.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to inject the hair follicle stimulating formulation of Gentz et al., because Naughton et al. teach the advantageous injection of a hair growth composition with like compounds.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use various mM of collagen, Daltons of dextran, or mM of glutamic acid, or μM of cysteine in the composition for hair follicle stimulation of Gentz et al. because the additional of different amounts of such compounds for desired effects is well within the preview of one of skill in the art and a matter of routine optimization.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA
January 12, 2004

CHRISTOPHER R. TATE
PRIMARY EXAMINER